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September 17, 2003

Date

David L. Parker

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Borje S. Andersson

Serial No.: 09/415,890

Filed: October 8, 1999

For: PHARMACOLOGICALLY

ACCEPTABLE SOLVENT VEHICLES

Group Art Unit: 1616

Examiner: Neil Levy

Atty. Dkt. No.:UTXC:528--1/DLP

I. AMENDMENT; AND II. RESPONSE TO OFFICIAL ACTION <u>DATED APRIL 24, 2003</u>

Commissioner for Patents P. O. Box 1450 Alexandria, VA 22313-1450

Sir:

This paper is submitted in response to the Official Action dated April 24, 2003, for which the three-month date for response was July 24, 2003. A request for a two-month extension of time is filed herewith, along with the required fee. The two-month extension will bring the due date to September 24, 2003, which is within the six-month statutory period. Should such request or fee be deficient or absent, consider this paragraph such a request and authorization to withdraw the appropriate fee under 37 C.F.R. §§ 1.16 to 1.21 from Fulbright & Jaworski L.L.P. Account No.: 50-1212/UTXC:528--1.

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I. AMENDMENT

Please amend the claims by:

- 1) canceling claims 16-23, 26-93 and 100-105,
- 2) amending claims 97, 99, 116, 133, 141-142, and
- 3) adding new claim 150.

as follows:

- 1.-93. (Cancelled)
- 94. (Withdrawn) The method of claim 93, where the acid is acetic acid.
- 95. (Withdrawn) The method of claim 93, where the dipolar aprotic solvent and/or acid is virtually eliminated from the solvent vehicle.
- 96. (Withdrawn) The method of claim 93, where removing the dipolar aprotic solvent and/or acid is by lyophilization.
- 97. (Currently Amended) The method of claim 93, A method for preparing a pharmaceutically acceptable solvent vehicle, the method comprising:
 - (a) obtaining a pharmaceuctically acceptable dipolar aprotic solvent and/or acid;
 - (b) mixing the dipolar aprotic solvent and/or acid in a pharmaceutically acceptable aqueous secondary solvent;
 - (c) removing more than 50% of the dipolar aprotic solvent and/or acid and aqueous secondary solvent; and
 - (d) further comprising-reconstituting the solvent vehicle composition by the addition of a pharmaceutically acceptable aqueous solvent.



98. (Previously Presented) The method of claim 97, wherein said pharmaceutically acceptable aqueous solution comprises water, saline solution, dextrose solution, aqueous lipid emulsion, glacial acetic acid, or lipid solution.

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99. (Currently Amended) The method of claim <u>9793</u>, further comprising the step of dissolving pimaricin in said dipolar aprotic solvent and/or acid prior to mixing in a pharmaceutically acceptable aqueous secondary solvent.

100.-105. (Cancelled)

106. (Withdrawn) The method of claim 93, wherein the dipolar aprotic solvent or acid is eliminated.

107. (Withdrawn) The method of claim 93, wherein the removing dipolar aprotic solvent or acid removes 95% of the dipolar aprotic solvent or acid.

108. (Withdrawn) The method of claim 107, wherein the removing dipolar aprotic solvent or acid removes 99% of the dipolar aprotic solvent or acid.

109. (Withdrawn) The method of claim 93, wherein said aprotic solvent comprises N,N-dimethylacetamide, castor oil, dimethylsulfoxide, 1,2,-propylene-diol, glycerol or polyethylene glycol-400.

110. (Withdrawn) The method of claim 109, wherein said aprotic solvent comprises N,N-dimethylacetamide.

111. (Withdrawn) The method of claim 109, wherein said aprotic solvent comprises castor oil.

112. (Withdrawn) The method of claim 109, wherein said aprotic solvent comprises dimethylsulfoxide.

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- 113. (Withdrawn) The method of claim 109, wherein said aprotic solvent comprises 1,2,-propylene-diol.
- 114. (Withdrawn) The method of claim 109, wherein said aprotic solvent comprises glycerol.
- 115. (Withdrawn) The method of claim 109, wherein said aprotic solvent comprises polyethylene glycol-400.
- 116. (Currently Amended) The method of claim <u>9793</u>, wherein said secondary solvent comprises aqueous lipid emulsion, water, saline solution, dextrose solution, glacial acetic acid, or lipid solution.
- 117. (Previously Presented) The method of claim 116, wherein said secondary solvent comprises an aqueous lipid emulsion.
- 118. (Previously Presented) The method of claim 117, wherein said aqueous lipid emulsion comprises emulsified fat particles of about 0.4 micron in diameter.
- 119. (Previously Presented) The method of claim 117, wherein said aqueous lipid emulsion comprises an aqueous soy bean lipid emulsion.
- 120. (Previously Presented) The method of claim 119, wherein said aqueous soy bean lipid emulsion comprises soy bean oil, lecithin, glycerin and water.
- 121. (Previously Presented) The method of claim 117, wherein said aqueous lipid emulsion comprises a lipid component that includes at least one vegetable oil and at least one fatty acid.
- 122. (Previously Presented) The method of claim 121, wherein said lipid component comprises at least about 5% by weight soybean oil and at least about 50% by weight fatty acids.
- 123. (Withdrawn) The method of claim 116, wherein said secondary solvent comprises water.
- 124. (Withdrawn) The method of claim 116, wherein said secondary solvent comprises saline solution.

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- 125. (Withdrawn) The method of claim 116, wherein said secondary solvent comprises dextrose solution.
- 126. (Withdrawn) The method of claim 125, wherein said dextrose solution comprises 5% to 70% dextrose in water.
- 127. (Withdrawn) The method of claim 126, wherein said dextrose solution comprises 5% or 10% dextrose solution.
- 128. (Withdrawn) The method of claim 116, wherein said secondary solvent comprises glacial acetic acid.
- 129. (Withdrawn) The method of claim 93, wherein said secondary solvent comprises a lipid solution.
- 130. (Withdrawn) The method of claim 93, wherein said secondary solvent comprises a parenteral infusion fluid.
- 131. (Withdrawn) The method of claim 93, wherein said solvent vehicle comprises anhydrous N,N-dimethylacetamide and polyethylene glycol-400.
- 132. (Withdrawn) The method of claim 93, wherein said solvent vehicle comprises glacial acetic acid and polyethylene glycol-400.
- 133. (Currently Amended) The method of claim <u>9793</u>, wherein said solvent vehicle comprises anhydrous N.N-dimethylacetamide and aqueous lipid.
- 134. (Previously Presented) The method of claim 133, wherein said aqueous lipid is an aqueous soy bean lipid emulsion comprising soy bean oil, lecithin, glycerin and water.
- 135. (Previously Presented) The method of claim 134, wherein said solvent vehicle comprises anhydrous N,N,-dimethylacetamide and an aqueous soy bean lipid emulsion comprising soy bean oil, lecithin, glycerin and water in a 1:10 volume ratio.

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- 136. (Previously Presented) The method of claim 134, wherein said solvent vehicle comprises anhydrous N,N,-dimethylacetamide diluted with 9 volumes 20% of an aqueous soy bean lipid emulsion comprising soy bean oil, lecithin, glycerin and water.
- 137. (Previously Presented) The method of claim 134, wherein said solvent vehicle further comprises normal saline or 5% dextrose solution.
- 138. (Withdrawn) The method of claim 93, wherein said solvent vehicle comprises anhydrous N,N-dimethylacetamide, polyethylene glycol-400 and 1,2-propylene diol.
- 139. (Withdrawn) The method of claim 93, wherein said solvent vehicle comprises anhydrous N,N-dimethylacetamide, polyethylene glycol-400, 1,2-propylene diol and dimethylsulfoxide.
- 140. (Withdrawn) The solvent vehicle of claim 139, wherein said solvent vehicle comprises anhydrous N,N,-dimethylacetamide, polyethylene glycol-400, 1,2-propylene diol and dimethylsulfoxide in equal volume ratios.
- 141. (Currently Amended) The method of claim <u>9793</u>, wherein said vehicle comprises glacial acetic acid, and wherein said vehicle further comprises anhydrous N,N,-dimethylacetamide, dimethylsulfoxide or an aqueous soy bean lipid emulsion comprising soy bean oil, lecithin, glycerin and water.
- 142. (Currently Amended) The method of claim 15093, wherein said solvent vehicle comprises glacial acetic acid, dimethylsulfoxide and an aqueous soy bean lipid emulsion comprising soy bean oil, lecithin, glycerin and water.
- 143. (Previously Presented) The method of claim 142, wherein said solvent vehicle comprises glacial acetic acid, dimethylsulfoxide, and an aqueous soy bean lipid emulsion comprising soy bean oil, lecithin, glycerin and water in a 2:6:3 volume ratio.

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- 144. (Withdrawn) The method of claim 98, wherein said pharmaceutically acceptable aqueous solution comprises water.
- 145. (Withdrawn) The method of claim 98, wherein said pharmaceutically acceptable aqueous solution comprises saline solution.
- 146. (Withdrawn) The method of claim 98, wherein said pharmaceutically acceptable aqueous solution comprises dextrose solution.
- 147. (Withdrawn) The method of claim 146, wherein said dextrose solution comprises 5% to 70% dextrose in water.
- 148. (Withdrawn) The method of claim 147, wherein said dextrose solution comprises 5% or 10% dextrose solution.
- 149. (Withdrawn) The method of claim 98, wherein said secondary solvent comprises a parenteral infusion fluid.

150. (New) The method of claim The method of claim 97, wherein said solvent vehicle comprises glacial acetic acid and an aqueous lipid emulsion.

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